



Suggested Formula	Blank Oral Chewable Treats (Solid Suspension, 60 x 3.8 mL Treats)	FIN	F 005 265v3
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
APIs**	TBD					
Stevia Powder	2.40	g				
Glycerin, USP***	24.0	mL				
Beef Flavor (Powder)	12.00	g				
Chew-A-Treat™ Compound A	87.76	g				
Chew-A-Treat™ Compound B	175.52	g				

**Note: APIs can be added by using 0.7 displacement factor to accordingly reduce Compound A and B in the 1:2 ratio.

***Note: Caprylic/Capric Triglyceride can be used to replace Glycerin to reduce stickiness.

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): Glycerin, Stevia Powder

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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SUGGESTED PREPARATION (for 60 x 3.8 mL Treats)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ___	Processing Error	Qty. to measure
APIs	TBD				
Stevia Powder §	2.40	g			
Glycerin, USP §	24.0	mL			
Beef Flavor (Powder)	12.00	g			
Chew-A-Treat™ Compound A	87.76	g			
Chew-A-Treat™ Compound B	175.52	g			

* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction

1.	<p><u>Mold lubrication:</u></p> <p>A. Lubricate all parts of the Chew-A-Treat™ Mold with suitable vegetable spray and set aside.</p> <p><u>Note:</u> Selected vegetable spray needs to be compatible with API(s) and all other ingredients within the formulation.</p>
2.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Chew-A-Treat™ Compound B to form a fine, homogeneous powder blend.</p> <p>B. Triturate the APIs to form a fine, homogeneous powder blend.</p> <p>C. By geometric addition, combine and mix the following ingredients together to form a homogeneous mixture:</p> <ul style="list-style-type: none"> -Fine, homogeneous powder blend (Step 2B) -Stevia Powder -Beef Flavor (Powder) -Fine, homogeneous powder blend (Step 2A) <p>D. Transfer the mixture (Step 2C) to a beaker and incrementally add the Glycerin.</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous moist blend.</p> <p><u>Note:</u> The mixture will have a sand-like texture. If it begins to stick to your stirring device or beaker, you can simply scrape it off and continue mixing.</p>



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3.	<p><u>Medium integration:</u></p> <p>A. Prepare a hot water bath to between 60°C and 65°C.</p> <p>B. Using the hot water bath, melt the Chew-A-Treat™ Compound A.</p> <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous thick, sticky liquid-like dispersion.</p> <p>C. Incrementally add the homogeneous moist blend (Step 2D) to the melted Chew-A-Treat™ Compound A (Step 3B).</p> <p><u>Specifications:</u> Continuously mix until homogeneous. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous thick, sticky paste-like dispersion.</p>		
4.	<p><u>Mold filling:</u></p> <p>A. Properly lubricate gloves (thumbs, forefingers, and palms) throughout filling.</p> <p>B. Continuing to heat the mixture between 60 to 65°C, remove a marble-sized quantity of the mixture at a time and roll it between your thumb and forefinger to form a cylinder. Pack the 60 mold cavities with these cylinders and scrape off any excess with pre-lubricated plastic scraper.</p> <p>C. Once the treats have been packed down with an extractor, apply a thin layer of lubricant to give a shiny surface.</p> <p>D. Allow the treats to cool at room temperature for at least 15 minutes and then remove them from the mold using the extractor.</p>		
5.	<p><u>Validation technique:</u></p> <p>A. Weigh 12 chewable treats.</p> <p>B. The final weight of each chewable treat shall not be less than 90% and not more than 110% of the theoretically calculated weight 5.13 g in accordance to USP guidelines.</p>		
6.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>		



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		Packaging Requirements		
	180 days, controlled room temperature, as per USP 795*.		Manually put into Chew-A-Treat blisters and cold seal with foil labels.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4	Keep in a dry place.
	2	Keep out of reach of children.	5	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	For Canine use only.	6	Keep at controlled room temperature (20°C – 25°C).
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	If allergic reactions occur, consult your pharmacist.			

* If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.

REFERENCES

1.	Lozenges/Troches. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 153.
2.	Glycerin. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 6th Edition</i> . American Pharmaceutical Association; 2009: 283.
3.	USP <795>. <i>United States Pharmacopeia XXXV / National Formulary 30</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 344.